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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,715	03/08/2002	Steven J. Catani	15117.0091	7318

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,715

Applicant(s)

CATANI ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 7-10, 12-33 and 35-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7-10, 12-33, 35-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 1/21/2005 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-4, 6, 11, 34 and 49-54 have been canceled.
2. Claims 5, 7, 9, 12, 33, 37 and 43 have been amended.
3. Remarks drawn to objections to specification and rejections under 35 U.S.C. 103.

Claims 5, 7-10, 12-33 and 35-48 are pending in the case. Applicants have indicated that claims 5, 7-10 and 12-48 are pending. This is a typographical error. Claim 34 has been cancelled. In the first part of the rejection under 35 U.S.C 103(a) of the previous office action mailed on 10/20/2004, it was indicated that claims 5, 7-10 and 12-32 are rejected. This is a typographical error. It should have been 12-36. The Examiner apologizes for the typo and thanks the applicant for bringing this to the Examiner's attention.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

The objection to the specification regarding the recitation of a hyperlink has been overcome by amendment.

Claim Rejections - 35 USC § 103

Claims 5,7-10 and 12-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al (US 5,498,709) and Claims 37-48 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Burke (AIC Book and Paper Group Annual, vol. 3, 1984, 13-58) in combination with Navia et al (US 5,498,709) are being maintained for reasons of record.

Regarding Claims 5,7-10 and 12-36 applicants argue that:

1. Navia's disclosure is a standard work up used in an organic reaction and there is little discussion of how to choose among several possible purification methods that a person of ordinary skill in the art might consider. There is not suggestion to try different sequence of steps.

2. Specifically Navia teaches transferring sucralose from a crude mixture including a first solvent (water) into a second solvent (ethyl acetate) and the product is isolated by further work up of the sucralose in the second solvent by contacting with a third solvent (water) but not at least partially immiscible with the first solvent (water). Navia does not teach the transfer of impurities and not sucralose into the second solvent nor does he suggest using a third solvent that is at least partially immiscible with the first solvent to extract sucralose, with sucralose recovered from the third solvent. Navia also does not teach the stepwise removal of impurities as is done in the present invention.

Applicants' arguments have been considered but are not found to be persuasive.

Navia et al teach the extraction of sucralose in an aqueous-brine solvent (first solvent) with impurities and extracting it with ethyl acetate (second solvent) to transfer impurities into the second solvent and then back-extract the ethyl acetate extracts with water (third solvent) to transfer the sucralose in to the water and retaining the second impurities in the first solvent (col. 9, line 54 through 10, lines 15-25; col. 6, lines 35-67). The sucralose is finally recovered by crystallization (col. 6, line 67).

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Even though Navia et al may not teach exactly what is transferred from one phase into another, one of ordinary skill in the art knows that in such liquid-liquid extractions there is no complete transfer of any given component from one phase to another. In the extraction process of Navia there would be transfer of impurities and sucralose between the solvents water and ethyl acetate, which are immiscible. Even though Navia does not teach the extraction of a partially purified composition one of ordinary skill in the art will recognize that the process is equally applicable to a composition that is not partially purified. Whether the impurities are removed at an earlier step or later step in the extraction process is not seen to be relevant. Hence it would have been obvious to one of ordinary skill in the art at the time the invention was made to use solvents of different polarity in a method of extraction as instantly claimed since the basic extraction steps and the type of solvents used is seen to be taught in the prior art.

Regarding claims 37-48 applicants argue that:

1. Claim 37 specifies that the second solvent have a lower Hildebrand parameter than the first solvent. Hence materials washed out tend to be those of lower polarity than sucralose. Impurities of higher polarity than sucralose are then removed from the partially purified sucralose by washing with a solvent having a higher Hildebrand solubility parameter. Thus both higher and lower polarity impurities are removed before any further purification using three different solvents based on their polarity and Navia does not teach this.

This is not found to be persuasive.

Applicants' arguments are directed to only the teachings of Navia and not Burke, which is drawn to Hildebrand parameters. Navia's teaching (as discussed above) deals with essentially cleaning the sucralose before final purification and his process is seen to use three different

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solvents based on polarity as taught by Burke. The teaching of Burke does suggest that when a compound is present in a solvent along with impurities either the compound or the impurities can selectively be extracted using a second solvent with a different Hildebrand parameter. Navia teaches the extraction process with water and ethyl acetate both of which according to Burke have very different Hildebrand parameters. Since Navia has successfully shown the removal of impurities using these two solvents one of ordinary skill in the art would use the same solvents. Navia's process is also seen to remove both higher and lower polarity impurities from sucralose. The order in which the two types of impurities are removed is not seen to be relevant and also not seen to be patentably distinct.

Conclusion

Claims 5, 7-10, 12-33 and 35-48 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

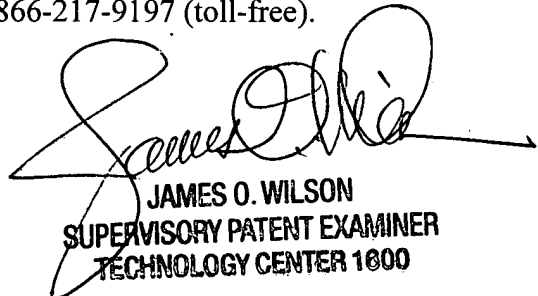
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654.

The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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